

REMARKS

Claims 1, 3-18, 20, 23-26 and 28-34 are pending after these amendments. Claims 4-17 and 20 have been amended to correct formalities. Thus, Applicant respectfully requests the withdrawal of the Examiner's objections. Reconsideration and allowance of the pending claims are respectfully requested, in view of the remarks below.

Rejection under 35 U.S.C. § 112

The Examiner rejected claim 19 under 35 U.S.C. § 112, as allegedly being indefinite. Claim 19 has been canceled without prejudice, rendering this rejection moot as to this claim.

Rejections Under 35 U.S.C. 102

The Examiner rejected claim 1 as allegedly anticipated by Campbell (US H1398). This rejection is respectfully traversed.

Claim 1 recites the step of providing a primer covalently bound to a non-nucleotide carrier macromolecule. The claim requires that the carrier macromolecule is selected from the recited group, which group includes a "synthetic polymer having nucleophilic functional groups." The Examiner alleges that, since the specification does not define the term "carrier macromolecule," and "since it is known that OH-group is a nucleophilic functional group" that fluorescein qualifies as a "synthetic polymer having nucleophilic functional groups."¹ The Examiner also alleges that fluorescein is a "synthetic polymer" since it comprises -CH monomers.²

Legal Background

It is first noted that the Federal Circuit has held that in the absence of an express intent to impart an alternate meaning to claim terms, the terms are to be given their ordinary meaning. The ordinary meaning must be determined from the standpoint of a person of ordinary skill in the relevant art. *Nystrom v. Trex Co.*, 374 F.3d 1105; 71 USPQ2d 1241 (Fed. Cir. 2004) (*quoting* *Teleflex Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002)). The Federal Circuit has also stated that normal rules of usage suggest a "heavy presumption" that claim terms carry their

¹ Office Action mailed 12/23/05, p. 4, line 2.

² *Id.* at line 4.

accustomed meaning in the relevant community at the relevant time. *ResQnet.com, Inc. v. Lansa, Inc.* 346 F.2d 1374; 68 USPQ2d 1619 (Fed. Cir. 2003). Claim construction always begins with the ordinary meaning of the claim language, and claims are not construed within a vacuum, but rather in the context of the specification. *Jansen v. Rexall Sundown, Inc.* 342 F.3d 1329; 68 USPQ2d 1154 (Fed. Cir. 2003).

As the Declaration of Samuel A. Lewis, Ph.D. explains (attached as Exhibit 1), fluorescein is neither a “macromolecule” nor a “synthetic polymer” according to the ordinary and accustomed meaning of those terms in the relevant art. At paragraph 3 of his Declaration, Dr. Lewis explains that a polymer is a molecule formed by combining sub-units into a chain. Since fluorescein does not comprise subunits, it is not a polymer. The Examiner asserted that fluorescein is a polymer of –CH units. But as Dr. Lewis explains at paragraph 4 of his Declaration, this use of the term is incorrect and is not within the ordinary meaning of the term in the fields of chemistry and molecular biology.

Since Campbell does not disclose a carrier macromolecule within the group recited in the claim, the claim is not anticipated by Campbell.

The Examiner rejected claim 18 as allegedly anticipated by Bronstein under 35 U.S.C. 102(b). This rejection is respectfully traversed.

The Examiner alleges that Bronstein anticipates claim 18 because Bronstein discloses a DNA probe attached to alkaline phosphatase, and a nucleic acid complementary to the DNA probe immobilized on a nitrocellulose membrane.³ The Examiner alleges that the nitrocellulose membrane is a “carrier macromolecule.”⁴

The Declaration of Samuel A. Lewis, Ph.D. explains at paragraph 7 that the ordinary and accustomed meaning of the term “carrier macromolecule” in the relevant art does not encompass a solid phase nitrocellulose sheet. The term “carrier” used in this context is understood to indicate that the macromolecule is moving during the assay, and excludes a solid phase such as a nitrocellulose membrane, which cannot carry another molecule.

³ Id. at p. 4.

⁴ Id. at p. 6.

The specification provides its own independent support for Dr. Lewis' explanation of the meaning of the term "carrier macromolecule." For example, note at paragraph 24 the specification states "In a particularly advantageous aspect of the invention, the carrier macro molecule is itself bound to a solid support." And later in the paragraph, "The solid support may take many forms such as... membranes..." Nitrocellulose sheets (or membranes) are a common form of "solid support," as clearly indicated by the context.

In response to the Applicant's previously submitted arguments, the Examiner notes that the claims do not require that the carrier macromolecule is bound to a solid support.⁵ However, the Applicant does not assert that the claims require the carrier macromolecule be bound to a solid support. Rather, the context of the specification itself excludes a nitrocellulose membrane from being within the meaning of the term "carrier macromolecule" as the term is used in the specification, since it refers to the nitrocellulose sheet by a separate term. Thus, the meaning adopted by the Examiner is not the ordinary meaning used in the art, and is in fact inconsistent with the use of the term in the art and in the specification. *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321; 70 USPQ2d 1508 (Fed. Cir. 2004) ("A technical term is not properly removed from its context in order to seek its meaning").

For the reasons explained above and in the Declaration of Dr. Lewis, Bronstein does not disclose or suggest a method of detecting the presence of a nucleic acid involving a first nucleic acid bound to a non-nucleotide carrier macromolecule, and a second nucleic acid bound to a non-nucleotide carrier macromolecule. Therefore, Bronstein cannot anticipate claim 18.

Rejections Under 35 U.S.C. 103

The Examiner rejected claim 1 as allegedly unpatentable over Campbell in view of Ausubel (USP 6,004,783) under 35 U.S.C. 103(a).

In order to establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference

⁵ Office Action mailed 12/23/05, p. 6, line 9.

teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 2142.

The deficiencies of Campbell are discussed above. Ausubel does not provide the limitations missing from Campbell, particularly in view of the amendment made to the claim. Since all of the claim limitations are not disclosed in the cited references (or by the knowledge of the person of ordinary skill in the art), the claims cannot be obvious over the asserted combination of references.

The Examiner has put forth several additional rejections of various claims under 35 U.S.C. 103(a), including combinations of:

Campbell in view of Ausubel, and further in view of Gold (claims 3-9, 11-13, 24-26, 28, 30-31);

Campbell, Ausubel, and Gold, and further in view of Landgren (claims 10, 14-17, 29, 32 33);

Campbell in view of Ausubel and Gold, and further in view of Yamane (claim 34);

Campbell, Ausubel, Gold, and Landegren, and further in view of Barany (claim 20).

None of these combined references provides the limitations missing from Campbell and Ausubel, as described above. Therefore, for the same reasons as described with respect to Campbell and Ausubel, the claims are not unpatentable in view of these combinations of references.

With respect to the rejection of claims 21-22, this rejection is moot in view of the cancellation of these claims.

Claim 23 was rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Walker (USP 5,470,723) in view of Westling (USP 5,700,921). The amendment of claim 23 renders moot this rejection.

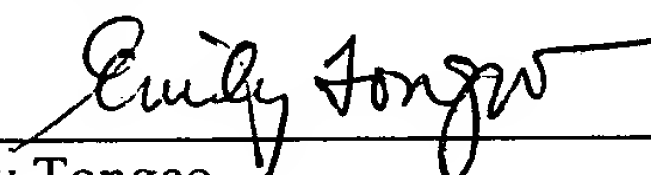
CONCLUSION

In view of the above, the pending claims are believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims, and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 577212000101. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 21, 2006

Respectfully submitted,

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